

Applicant : Gautam Khurana et al.
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Attorney's Docket No.: 14256-002001

REMARKS

The Examiner rejected claims 1, 3, 4, 5, 10-12, 14, 21-27, and 29, while allowing claims 6-9 and 15-20. Claims 30-40 have been added herein. Thus, claims 1, 3-12, 14-27, and 29-40 are pending.

In addition, claims 1, 5, 11, 12, 14, 15, 17, 21, 22, 23, and 29 have been amended. Specifically, claim 1 has been amended to recite that the tissue site is of an animal or human and that the gene delivery device is graspable. Support for these amendments can be found throughout Applicants' specification (see, e.g., Examples 1 and 2 and page 8, lines 17-19). Claims 5 and 14 have been amended to recite that the nucleic acid is DNA. Support for these amendments can be found at, for example, page 4, lines 4-6. Independent claims 11 and 12 have been amended to recite the limitations in original claim 15. Claim 15 has been amended to recite that the nucleic acid is RNA, an anti-sense molecule, a triple-helix-forming nucleic acid, an aptamer, or a ribozyme. Support for this amendment can be found at, for example, page 4, lines 4-6. Claim 17 has been amended to recite a graspable element as opposed to a graspable surface. Claim 21 has been amended to recite that the contact surface is detachably connected to the housing. Support for this amendment can be found at, for example, Figure 2B and page 9, lines 17-21. Claim 22 has been amended to recite that the contact surface is connected to the housing via an adapter. Support for this amendment also can be found at, for example, Figure 2B and page 9, lines 17-21. Claim 23 has been amended to recite that the contact surface is adjustable to an angle that is 0-180° with respect to the longitudinal axis of the housing. Support for this amendment can be found at, for example, page 34, lines 3-8 and original claim 23. Claim 29 has been amended to recite that the contact surface is connected to the housing. Support for this amendment can be found in, for example, Figures 1 and 2. Thus, no new matter has been added by these amendments.

New claim 30 recites that the nucleic acid is RNA, an anti-sense molecule, a triple-helix-forming nucleic acid, an aptamer, or a ribozyme. Support for this claim can be found at, for example, page 4, lines 4-6. New claim 31 recites a device having a housing and a contact surface, wherein the contact surface is adjustable to an angle that is 0-180° with respect to the longitudinal axis of the housing. Support for this claim can be found at, for example, original claims 21 and 23 and page 34, lines 3-8. Dependent claims 32, 33, 34, 35, and 36 are similar to

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dependent claims 22, 24, 25, 26, and 27, respectively. Claim 37 recites that the nucleic acid is DNA, while claim 38 recites that the nucleic acid is RNA, an anti-sense molecule, a triple-helix-forming nucleic acid, an aptamer, or a ribozyme. Support for these new claims can be found at, for example, page 4, lines 4-6. Claim 39 recites that the contact surface is detachable from the housing. Support for this claim can be found at, for example, Figure 2B and page 9, lines 17-21. Dependent claim 40 is similar to dependent claim 18. Thus, no new matter has been added by these new claims.

In light of the following remarks, Applicants respectfully request reconsideration and allowance of claims 1, 3-12, 14-27, and 29-40.

Withdrawn Rejections

Applicants acknowledge withdrawal of the rejections 35 U.S.C. §§ 102(b), 103(a), and 112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 21-27 and 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that "it is unclear whether the housing and contact surface are separated or connected," suggesting that Applicants amend the claims to provide a clearer picture of the device.

The meaning of claims 21-27 and 29 as previously written is clear and definite. To further prosecution, however, independent claim 21 has been amended to recite that the contact surface is detachably connected to the housing. In addition, independent claim 29 has been amended to recite that the contact surface is connected to the housing. Thus, the meaning of claims 21-27 and 29, as amended, is clear and definite.

In light of the above, Applicants respectfully request withdrawal of the rejection to claims 21-27 and 29 under 35 U.S.C. § 112, second paragraph.

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Rejections under 35 U.S.C. § 102(e)

The Examiner rejected claims 1, 3, 5 and 10 under 35 U.S.C. § 102(e) as being anticipated by MacCall *et al.* (U.S. Patent No. 6,004,806). Specifically, the Examiner stated that:

MacCall *et al.* disclose therapeutic compositions comprising a ribozyme directed against bacterial infection formulated into a cream. MacCall *et al.* disclose that said cream can be applied to the site of infection (col. 12, lines 18-28). Applying cream to the site of the infection (either wounded or intact skin/mucosa) comprises applying the cream to a finger (a contact surface) and subsequently contacts the finger with cream to the tissue site, wherein such contacting can be moving the finger back and forth or in circular motion at the tissue site. Therefore, MacCall *et al.* disclose the instantly claimed invention.

Applicants respectfully disagree. To further prosecution, however, claim 1 has been amended herein to recite that the gene delivery device is graspable. At no point does the MacCall *et al.* patent teach or suggest (1) providing a graspable gene delivery device having a contact surface, (2) applying the pharmaceutical composition to the contact surface, and (3) contacting the contact surface to the tissue site by moving the contact surface across the tissue site. Thus, the MacCall *et al.* patent does not anticipate the presently claimed invention.

In light of the above, Applicants respectfully request withdrawal of the rejection to claims 1, 3, 5 and 10 under 35 U.S.C. § 102(e).

The Examiner also rejected claims 1, 3, 4, and 5 under 35 U.S.C. § 102(e) as being anticipated by the 1987 Vicente *et al.* abstract. Specifically, the Examiner stated that:

Vicente *et al.* teach a method of inoculating virus to plant by brushing the leaves. Such method also delivers DNA or RNA to a tissue site by a device with a contact surface that is bristle (see line 2 of abstract). Therefore, Vicente *et al.* disclose the instant claimed invention.

Applicants respectfully disagree. The 1987 Vincent *et al.* abstract discloses brushing gamma interferon, a polypeptide, onto plant leaves. To further prosecution, however, claim 1 has been amended herein to recite delivering a pharmaceutical composition to a tissue site of an animal or human. At no point does the 1987 Vincent *et al.* abstract teach or suggest delivering a pharmaceutical composition to a tissue site of an animal or human. Thus, the 1987 Vincent *et al.* abstract does not anticipate the presently claimed invention.

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In light of the above, Applicants respectfully request withdrawal of the rejection to claims 1, 3, 4, and 5 under 35 U.S.C. § 102(e).

In addition, the Examiner rejected claim 21 under 35 U.S.C. § 102(e) as being anticipated by the Serra *et al.* patent (U.S. Patent No. 5,681,335). Specifically, the Examiner stated that:

Serra *et al.* disclose a mini brush that has soft, flexible bristles with a lumen for delivering pharmaceutical compositions to dissolve a fibrinous obstruction (see Figure 1, and abstract). Therefore, Serra *et al.* disclose the instantly claimed invention.

Applicants respectfully disagree. To further prosecution, however, claim 21 has been amended herein to incorporate that limitations set forth in original claim 22. As acknowledged by the Examiner, original claim 22 is free of the prior art. Thus, the Serra *et al.* patent does not anticipate claim 21 as amended.

In light of the above, Applicants respectfully request withdrawal of the rejection to claim 21 under 35 U.S.C. § 102(e).

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 11, 12 and 14 under 35 U.S.C. § 103(a) as being unpatentable over the 1987 Vicente *et al.* abstract. Specifically, the Examiner stated that:

It would have been obvious to one of ordinary skill in the art to make a kit with the nucleic acid, a dye and a delivery device as taught by Vincent *et al.* Vincent *et al.* teach that brush can be used to deliver viral DNA to plant tissues. The ordinary artisan would have been motivated to include the nucleic acid in such a kit to make it easy for the inoculation process. The ordinary artisan would have been motivated to include a dye to monitor the site of monitor whether the composition has reached the desired tissue site. The ordinary artisan would have a reasonable expectation of success because making a kit with the brush and viral DNA stock and mixing a dye in the pharmaceutical composition is a routine practice. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Applicants respectfully disagree. Again, the 1987 Vincent *et al.* abstract discloses brushing gamma interferon, a polypeptide, onto plant leaves. To further prosecution, however, independent claims 11 and 12 have been amended herein to incorporate that limitations set forth

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in allowable claim 15. Thus, the claims 11, 12, and 14, as amended, are not rendered obvious by the 1987 Vincent *et al.* abstract.

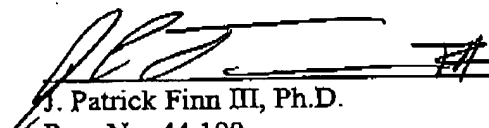
In light of the above, Applicants respectfully request withdrawal of the rejection to claims 11, 12, and 14 under 35 U.S.C. § 103(a).

CONCLUSION

Applicants submit that claims 1, 3-12, 14-27, and 29-40 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned agent at the telephone number below if such will advance prosecution of this application. The Commissioner is authorized to charge any fees or credit any overpayments to Deposit Account No. 06-1050. Please change the Attorney Docket No. to 14256-002001. Attached is a marked-up version of the changes being made by the current amendment.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claims 1, 5, 11, 12, 14, 15, 17, 21, 22, 23, and 29 have been amended as follows:

--1. (Amended Twice) A method for delivering a pharmaceutical composition comprising a nucleic acid to a tissue site of an animal or human, comprising the steps of:

providing a graspable gene delivery device comprising a contact surface;
applying said pharmaceutical composition to said contact surface; and
contacting said contact surface to said tissue site, wherein said contacting is by moving said contact surface across said tissue site.

5. (Amended Once) The method according to claim 1, wherein said nucleic acid is [selected from the group consisting of] DNA[, RNA, anti-sense molecules, triple-helix-forming nucleic acids, aptamers, and ribozymes].

11. (Amended Twice) A kit, comprising:

a gene delivery device comprising a contact surface for contacting a tissue, wherein said contact surface comprises bristles; and

a pharmaceutical composition comprising a nucleic acid, a polymerizeable compound,
and a polymerizing agent.

12. (Amended Twice) A kit, comprising:

a gene delivery device comprising a graspable surface for attachment to a contact surface;
at least one contact surface for attachment to said graspable surface, wherein said contact surface comprises bristles; and[:]

a pharmaceutical composition comprising a dye or other detectable moiety, a
polymerizeable compound, a polymerizing agent, and a nucleic acid.

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14. (Amended Once) The kit according to claim 11 or 12, wherein said nucleic acid is [said nucleic acids are selected from the group consisting of] DNA[, RNA, anti-sense molecules, triple-helix-forming nucleic acids, aptamers, and ribozymes].

15. (Amended Once) The kit according to claim 11 or 12, wherein said nucleic acid is RNA, an anti-sense molecule, a triple-helix-forming nucleic acid, an aptamer, or a ribozyme [further comprising a polymerizeable compound and a polymerizing agent].

17. (Amended Once) The kit according to claim 11 [or 12], wherein said gene delivery device comprises a graspable element [surface] having[,] a longitudinal axis, and said contact surface is detachable from said graspable element.

21. (Amended Twice) A device for delivering a pharmaceutical composition to a tissue, comprising:

a housing having a first end and a second end and defining a lumen, said first end comprising an opening;

a contact surface for contacting a tissue, wherein said contact surface comprises a plurality of bristles at least partially surrounding said opening, wherein said contact surface is detachably connected to said housing.

22. (Amended Once) The device of claim 21, wherein said contact surface is connected to said housing via an adapter [detachable from said housing].

23. (Amended Once) The device of claim 21, wherein said contact surface is adjustable to an angle that is [at a] 0-180° [angle] with respect to the longitudinal axis of the housing.

29. (Amended Twice) A kit comprising a device for delivering a pharmaceutical composition to a tissue, and a pharmaceutical composition comprising a nucleic acid, wherein said device comprises:

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a housing having a first end and a second end and defining a lumen, said first end comprising an opening;

a contact surface for contacting a tissue, wherein said contact surface comprises a plurality of bristles at least partially surrounding said opening, and wherein said contact surface is connected to said housing.

Claims 30-40 have been added as follows:

30. The method according to claim 1, wherein said nucleic acid is RNA, an anti-sense molecule, a triple-helix-forming nucleic acid, an aptamer, or a ribozyme.
31. A device for delivering a pharmaceutical composition to a tissue, comprising:
a housing having a first end and a second end and defining a lumen, said first end comprising an opening;
a contact surface for contacting a tissue, wherein said contact surface comprises a plurality of bristles at least partially surrounding said opening, wherein said contact surface is connected to said housing, and wherein said contact surface is adjustable to an angle that is 0-180° with respect to the longitudinal axis of said housing.
32. The device of claim 31, wherein said contact surface is connected to said housing via an adapter.
33. The device of claim 31, wherein said lumen further comprises a first and second channel, said first and second channel sharing a common wall.
34. The device of claim 31, wherein said second end of said housing is connectable to a syringe or conduit-tubing.
35. The device of claim 34, wherein said syringe and conduit tubing are double-barreled.

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36. The device of claim 31, wherein said first end comprises a plurality of openings.
37. The kit according to claim 29, wherein said nucleic acid is DNA.
38. The kit according to claim 29, wherein said nucleic acid is RNA, an anti-sense molecule, a triple-helix-forming nucleic acid, an aptamer, or a ribozyme.
39. The kit according to claim 29, wherein said contact surface is detachable from said housing.
40. The kit according to claim 29, wherein said contact surface comprises a plurality of contact surfaces, each of which are differently angulated with respect to the longitudinal axis of said housing.